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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/871,863      | 06/01/2001  | Randolph H. Watkins  | DI-5717             | 1448             |

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EXAMINER

MENON, KRISHNAN S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1723

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DATE MAILED: 10/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

En

**Office Action Summary**

Application No.

09/871,863

Applicant(s)

WATKINS ET AL.

Examiner

Krishnan S Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-28, drawn to the apparatus dialyzer, classified in class 210, subclass 435.
- II. Claims 29-32, drawn to the method of dialysis, classified in class 210, subclass 646.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed by a different (any) dialyzer and the apparatus as claimed can be used for a materially different process like ultrafiltration or microfiltration.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Barrett, attorney of record on 9/30/2002 a provisional election was made with out traverse to prosecute the invention of I, claims 1-28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 29-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "header" in line 1. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, the header will be considered as the fluid flow channel in the blood inlet.

Claim 18 recites the limitation "dialyzer inlet header" in line 1. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, the header will be considered as the fluid flow channel in the blood inlet.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the claim is an incomplete sentence, and the plurality of curved vanes is not linked to anything. For examination purposes, the plurality of curved vanes will be included as part of the fluid flow channel in the blood inlet.

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*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,4 ,5,8,12, 14,15 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kanno et al (US 4,201,673).

Instant claims 1, 12: Kanno (673) discloses a dialyzer with a header comprising a body designed to be attached to the dialyzer (24-fig 3), an inlet channel with axial flow to the fiber bundle and which is diverted in the radial direction as it exits the channel by a modifying member (27-fig 3, col 3 lines 65-68).

Instant claims 4,5, 14,15: the inlet channel is located at a center to the body and is sealed to the dialyzer casing (fig 3)

Instant claim 8: the member modifying the fluid flow obstructs the flow as it exits the channel (20,27-fig 3)

Instant claim 20: the dialyzer has a dialysate inlet and outlet defining fluid flow radial to the fiber bundle (6,7 -fig 1)

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 2,6,9-11, 13,16-19, and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanno (673) in view of Heilmann et al (US 6,053,967).

Instant claims 1, 12: Kanno (673) discloses a dialyzer with a header comprising a body designed to be attached to the dialyzer (24-fig 3), an inlet channel with axial flow to the fiber bundle and which is diverted in the radial direction as it exits the channel by a modifying member (27-fig 3, col 3 lines 65-68). The inlet header is located at a center of the body (fig 3) as in instant claim 26.

Kanno (673) does not disclose a curved channel as in instant claims 6 and 16, a plurality of curved vanes extending from a portion of the body of the header as in instant claims 2, 10, 11, 13, 18, 19, 22 and 23, a disc located under the an exit opening of the inlet fluid channel as in instant claims 9, 17, 24 and 25, and the plurality of vanes impart a circular motion as in instant claim 21.

Heilmann (967) teaches an inlet header for a blood filter application comprising a centrally located inlet with axial flow changing to radial flow as the flow exits the inlet (fig 1, 2), a disc shaped obstruction (26-fig 2) in the flow path and there are a plurality of curved vanes (28-fig 2) in the curved channel of the exit of the inlet flow imparting a circular motion to the fluid as it enters the interior of the header. It would be obvious to one of ordinary skill in the art at the time of invention

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to use the design of the header of Heilmann (967) in the teachings of Kanno (673) as alternate but equivalent to the header of Kanno (673) for equivalent function.

2. Claims 3,7,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanno (673) in view of Heilmann et al (US 967). as applied to claims 2,6,9-11, 13,16-19, and 21-26 above, and further in view of Maloney Jr et al (US 5,830,370).

Kanno (673) in view of Heilmann (967) does not disclose eight vanes in the inlet header channel as in instant claims 3,7,27 and 28. Maloney (370) teaches eight vanes in the inlet channel as an impeller attached to a rotating fiber bundle of a dialyzer (205-fig 10 A and B, col 13 line 23- col 14 line 14) It would be obvious to one of ordinary skill in the art at the time of invention to use eight vanes as taught by Maloney (370) instead of six vanes as taught by Heilmann (967) as alternate but equivalent for equivalent function.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fiber bundle with flow diversion vanes are disclosed in Chahine (US 5,500,134) and eight vane design for blood pump in Reeder et al (US 6,217,826 B1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone numbers for the organization

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where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan S. Menon  
Patent Examiner

  
W. L. WALKER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700